Quality and Accuracy - Specimen Acceptability and Transport Guidance

Quality and accuracy

Pathology and Laboratory Medicine recognizes that the quality and accuracy of laboratory results can only be assured when specimens and test requests meet specific criteria for collection, labeling, and integrity. Laboratories must adhere to strict standards respecting the identity and integrity of specimens. This policy applies to all specimens and test requests submitted to the laboratory.

Each sample is evaluated for sample preservation. In general, no sample is refused for the reason of improper quantity or storage if the accuracy of any test result obtained may not be compromised by deficiencies in this area. However, if the ability to achieve a result may be compromised the referrer will be contacted about the improper sample container.

This document outlines the first level of screening for specimen acceptability.

Criteria for acceptance / specimen rejection criteria

Reasons for rejecting a sample may include, but is not limited to the following:

- Improper labeling: mislabeled/unlabeled
- Improper collection container
- Not adhering to special collection requirements when applicable (e.g. draw the sample in a pre-chilled tube)
- Excessive delay between collection and receipt in the laboratory
- Improper timing of collection
- Specimen damaged in transit
- Specimen not properly sealed (leaking)
- Specimen received with needle still attached
- Insufficient sample for analysis
- Specimen not stored properly
- Clotted/hemolyzed blood specimen
- Specimens contaminated and/or containing substances or particles that interfere with testing or extraction
- Expired blood tube
- For Transfusion Services, any hospital registered specimen that is not designated in the Hospital Information System as having been "collected" by the nurse is automatically rejected.

Labelling of Sample Containers

A positive link between the patient and sample must be present to avoid medical errors such as switched or mislabeled samples prior to accessioning. Two identifiers on the specimen containers/slides must be matched to a completed requisition to unequivocally identify the patient for whom the test is ordered.

The patient's full name and unique identifier on the specimen container must completely match the patient's full name and unique identifier on the requisition.

Do not use "pre-named" tubes/containers

A specimen is mislabeled when the requisition bears the name of one patient and the accompanying specimen bears the name of another patient.

Mismatched specimens are defined as specimens that are submitted with a requisition on which the identifying information does not exactly match that which appears on the specimen (e.g., a common name is used on the specimen and the formal name is used on the requisition).

The laboratory reserves the right to refuse improperly labeled specimens.

Specimens collected for laboratory testing must be labeled with a firmly and permanently attached computer generated label.

Label tube at the patient's bed side (or outpatient chair) using information from the arm band (or identification card). For out-patients, use computer generated label(s). If computer generated labels are not available, manually labeled tubes must be initialed by the collector.

Under no circumstances will a specimen be returned to the ward/clinic

All specimens must be legibly labelled at minimum with:

- Patients first and last name (or unique code in the case of anonymous testing) and
- At least one unique identifier such as Provincial Health Card Number, Medical Record #, Clinic #, chart #)
- Date of collection and time of collection (if applicable)
- Label is placed lengthwise on the tube without obscuring the level of blood in the tube or any other patient demographic label
- Label must not obscure the level of blood in the tube.

Glass slides

All glass slides (stained and unstained sections) must be labelled using lead pencil, etching or indelible ink labels. Note: The actual slide must be labelled not the slide container.

Unlabeled specimens

Unlabeled samples received without a requisition will be rejected. Unlabeled samples received with a requisition will be rejected if they can be recollected and are not irretrievable (e.g., venous blood samples). The physician/nurse/floor will be notified so that a new specimen may be drawn.

Exceptions: difficult-to-collect and irretrievable specimens

Definition:

Irretrievable - impossible to recover; describes something that cannot be retrieved, restored, fixed or put right; unrecoverable

Procedures for difficult-to-collect are necessarily different from those for samples which may readily be collected. The following list is not inclusive but indicates those samples to which special attention should be paid by both the physician and the laboratory.

Examples:

- Histopathology specimens including biopsies
- Cytology specimens (Other than PAP's, 'voided' urines and sputums)
- Body fluids: Synovial fluid, CSF, Pleural, Pericardial
- Blood cultures in height of fever
- Abscess fluids
- Kidney stones
- Intrauterine devices (IUD) for culture
- Specimens from neonates (Transfusion medicine samples excluded)
- Arterial blood gases and other arterial specimens
- Any prenatal, perinatal or fetal specimen
- Some DNA samples

Process:

1. The Physician's office/nursing unit will be contacted. **The laboratory will make no effort to verify the identity of the patient or alter the requisition in any way.**
2. The person responsible for collecting the specimen may be permitted to come to the laboratory to identify (re-label) the specimen only if it is an irretrievable sample.

Authorization to proceed with testing in any of the above situations may be given by the medical Lab Director or designate. In this case, the sample is accessioned and test results will be accompanied by a disclaimer.

Note: Irretrievable specimens should never be transported via the pneumatic tube

Requisitions

Each test request should be made on the laboratory's requisition form or by Laboratory Information System request; if an incorrect form is used, the laboratory may request additional information that has not been provided. In this case a request will be put forth for the submitting party to fill out the requisition form of the host Laboratory.

When requesting specialized/uncommon tests, please refrain from using abbreviations/acronyms/short forms/antiquated names. Instead, write out the full name of the commonly accepted test name to ensure unambiguous interpretation.

Molecular genetics test requests are accepted only from a Medical Geneticist, Pathologist, or Clinician with experience in Genetics, Genetic Counselor (with an accompanying clinician of record) or Laboratory Director.

Labeling of requisitions:

Requisitions received with specimens **must** include:

1. Patient's first and last name
2. Date of birth
3. Gender
4. One of the following:
    1. Provincial Health Card Number (PHN) and Province
    2. Hospital Patient Identification Number (MRN)
5. Full name of the referring physician and the CPSO number
6. Complete address for the referring physician including email and fax number
7. Collection/procedure time, collection date and the name of the person who collected the specimen
8. Relevant clinical / family history, treatment, medication, special instructions, disease status
9. Specimen type and origin – source/site, surgical number

For Genetic testing:

10. Full name of the genetic counsellor (if applicable) and contact information
11. Collection method
12. Reason for referral
13. Race and Ethnicity

Discipline-specific criteria and instruction

Hematology:

The following specimens for CBC testing will be rejected:

- Clotted specimens
- 4.0 mL EDTA tubes filled with less than 1.0 mL of blood or 3.0 mL EDTA tubes filled with less than 0.5 mL of blood
- Any sample that the lab has been informed was drawn from the wrong patient
- CBC samples received > 48 hours after the blood has been drawn
    - **Note:** CBC samples processed >24 hours and <48 hours after the Blood has been drawn should have a CBC comment "CBC specimen is greater than 24 hours old, interpret CBC results with caution" attached to the report.
- Any sample that appears to have been exposed to extremes of temperature

Blood Transfusion Services:

- Any specimen that is not designated in the Hospital Information System as having been "collected" by the nurse is automatically rejected

Flow Cytometry:

- Specimens that have been refrigerated, severely hemolyzed, clotted, under-filled, wrong anti-coagulant , not maintained at room temperature, and >30 hours old may be rejected..
- Body fluids, bone marrow, fine needle aspirations, other tissue specimens will not be rejected.

Surgical Pathology:

- All tissue specimens that are submitted are considered irretrievable. It is the department's policy that no specimens submitted to the **Surgical Pathology** lab are rejected. All efforts are to be made to identify a patient to the specimen and/or requisition.
- All specimens **must** have an accompanying requisition.

Genetics

- DNA for testing is to be submitted in TRIS-HCL or H2O only (no EDTA). However, blood is the preferred specimen type and DNA received that does not meet laboratory standard will be rejected or will be issued as inconclusive reports.
- Clotted samples will be rejected as are samples sent in tubes containing anticoagulants that will inhibit extraction and testing (I.e. green top tubes containing sodium or lithium heparin submitted for molecular testing)

- Due to issues related to the validation of our test methods, the availability of reagents for DNA extraction and the amount and/or quality of DNA obtained from other tissues, MSH cannot generally accept other tissue types (e.g., buccal swabs, fresh tissue or blood spot cards) for DNA extraction and testing. Contact the Laboratory Manager or Director for cases where collection of blood or Formalin fixed tissue samples for DNA extraction is not feasible.
- All specimens MUST have an accompanying requisition
- **Tissue requirements:**
  - Preferred: tumour tissue block.
  - Alternate: Unstained slides for Immunohistochemistry or FISH submit on positively charged slides. Unstained slides for Molecular tests must be on Uncharged slides. For RNA/DNA based molecular tests, follow appropriate molecular microtomy cleaning protocols between each tissue block (see Paraffin Block Cutting Instructions). All biomarkers are validated with tissue fixed in 10% neutral buffered formalin for 6 to 72 hours (as per CAP/ASCO guidelines). Microwave processed and decalcified samples are not suitable for testing. Mercurochrome use as a dye marker is not recommended.

Transport and delivery to MSH laboratories

Transport and Integrity:

Blood samples must arrive in sealed tubes. Blood tubes should be opened only at the laboratory.

Date of collection/delivery:

In general, routine blood samples should be delivered to the laboratory **no more than 2 hours after** phlebotomy.

Specimen packaging and transport

Packaging instructions

Samples should be packaged in a way as to maintain patient confidentiality and prevent leakage and/or contamination to couriers and porters.

The quality of some tests will be affected if samples are collected in the wrong containers, stored at extreme temperatures or delayed in transit. This may result in the failure of the test.

Shipping instructions: Collect and ship samples on the same day. Samples should be received within 24 to 48 hours. **Note:** Genetics and Pathology laboratories are closed on weekends and holidays, please ship Monday to Thursday.

Specimens should be packaged in compliance with IATA P.I. 650 shipping standards and the Transportation of Dangerous Goods Act summarized below:

- A water tight primary receptacle (e.g., blood specimen tube)
- A water tight secondary receptacle with sufficient absorbent material to absorb the fluid in the primary receptacle
- An outer package of adequate strength for its intended use

The outside of the package should have a label (see below) indicating **"Non-biohazardous, Non toxic material"** and of no commercial value. Use the following as a label:

Mount Sinai Hospital
Pathology and Laboratory Medicine,
600 University Ave.,
[Specify 6th Floor for Anatomical Pathology or 11th floor for Core Lab or Genetics]
Toronto, Ontario
M5G 1X5
Canada

Diagnostic Specimen

Non-biohazardous, Non-toxic material and of no commercial value

Tests referred out from MSH laboratories

An up-to-date and completed requisition for the referral lab must be received with the sample.

Instructions for sample requirements, forms, labeling, and requisition requirements are available on the referral laboratory website(s). **All** pages of requisition are required.

References

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4. The Canadian College of Medical Geneticists (2002) CCMG Molecular Genetics Guidelines. http://www.ccmg-ccgm.org.
5. CAP, Laboratory Accreditation Program, All Common Checklist, General Laboratory Checklist, 2017
6. CLSI H18-A4. Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline – Fourth Edition, volume 30 number 10; 2010. ISBN 1-56238-724-3.
7. CLSI H3-A6. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard – Sixth Edition, volume 27 number 26; 2007. ISBN 1-56238-650-6.
8. CMLTO, Pocket Portfolio, Test Performance Checklist, 1999.
9. Ontario Association of Medical Laboratories (OAML) guideline, 2007.
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11. The Guide to the Collection and Submission of Specimens, Laboratory Services Branch, Ontario Ministry of Health, April 1992 CLSI Specimen Collection, ISBN 1-56238-291-8,SC2-L (H3-A4).
12. Collection of Diagnostic Venious Blood Specimens, CSLI guideline: GP41, 7th Edition, 2017.